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TITLE: “Evaluation of the King-Devick Test to Assess Eye Movements and the Performance of Rapid Number Naming in Concussed and Non-Concussed Service Members”

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Approved for public release; distribution unlimited

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14. ABSTRACT
This study's objective is to determine to what extent the King-Devick Test results discriminate healthy individuals from both their pre-Combatives baseline and their post-Combatives assessment, to determine to what extent individuals diagnosed as having an mTBI event differ from their King- Devick Test pre-Combatives baseline, and to determine to what extent individuals who report a history of concussion during their pre-Combatives baseline differ from those who have not reported a prior concussive event.

15. SUBJECT TERMS Nothing listed

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
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Unclassified	Unclassified	Unclassified			19b. TELEPHONE NUMBER *(include area code)*

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Introduction:

The primary study objective is to determine the concurrent validity, sensitivity, and specificity of the King-Devick Test to cognitive impairment of attentional processes associated with acute mild traumatic brain injury (mTBI) in service members. The secondary objective it to explore the neurophysiological and neurostructural changes in the brain associated with both combatives training and acute concussion.

Keywords:

MTBI, concussion, neurocognitive

Accomplishments:

What were the major goals of the project?

1) Initiate, Plan and Design Study [Months 2-3]

2) Execute Study (collect and analyze data) [Months 3-9]

3) Conclude Study [Month 10]

What was accomplished under these goals?

Two protocols were approved.

1) (A-18002) Evaluation of the King-Devick Test to Assess Eye Movements and the Performance of Rapid Number Naming in Concussed and Non-Concussed Service Members.
2) (A-18002.2) Imaging Assessment of Neurological Changes Associated with Subconcussive and Concussive Events in US Soldiers.

In addition we -

1) Hired and trained a new technician to assist with data collection.
2) Major renovations to data collection RV.
3) Attained Fort Benning command approval to park RV outside Combatives school house.
4) Received approval of an amendment to the protocol with respect to the addition of our new team member.
5) Approved for a one-year no-cost extension in order to complete the study.
6) Commenced recruitment and data collection (11 participants enrolled as of 25 July 16).

What opportunities for training and professional development has the project provided?

Nothing to Report

How were the results disseminated to communities of interest?

Updates have been briefed to the quarterly Noninvasive Neuro-Assessment Devices In progress Review Meetings (USAMRMC CCCRP).

What do you plan to do during the next reporting period to accomplish the goals?

Complete data collection. Analyze data and provide findings.

Impact

The findings from this project has the potential to impact policy for screening concussion during training in CONUS. The secondary and tertiary effects may result in continued research within other military populations and operational environments. This policy change would come through dissemination of findings to USAMRMC, MEDCOM, OTSG, and DVBIC. The results of the second protocol aimed at exploring the neuroanatomical and physiologic changes associated with combatives training (both subconcussive and concussive events) will inform the community of the sensitivity and specificity of various brain imaging techniques compared to neurocognitive measures of interest.

What was the impact on the development of the principal discipline(s) of the project?
Nothing to Report

What was the impact on other disciplines?
Nothing to Report

What was the impact on other disciplines?
Nothing to Report

What was the impact on technology transfer?
Nothing to Report

What was the impact on society beyond science and technology?
Nothing to Report

Changes/Problems:

Changes in approach and reasons for change
Nothing to Report

Actual or anticipated problems or delays and actions or plans to resolve them
Unexpected administrative and procedural changes at the IRB of record and repairs to the RV resulted in a delay in data collection. To mitigate this delay, a one-year no-cost extension was attained. Data collection has commenced (25 July 2016).

Changes that had a significant impact on expenditures
Nothing to Report

Significant changes in use or care of human subjects, vertebrate animals, biohazards, and/or select agents
Nothing to Report

Products:
Nothing to Report

Participants & Other Collaborating Organizations
What individuals have worked on the project?

Name:	Dr. Michael Dretsch
Project Role:	Principal Investigator
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	3.6
Contribution to Project:	Dr. Dretsch serves as the overall study PI on this research project.

Name:	Jenifer Fauth
Project Role:	Project Director
Researcher Identifier (e.g. ORCID ID):	
Nearest person month worked:	12
Contribution to Project:	Jenifer Fauth serves as the Project Director and on-site lead for this research project.

Has there been a change in the active other support of the PD/PI(s) or senior/key personnel since the last reporting period?

Additional key personnel hired and added to protocol

What other organizations were involved as partners?
Auburn University MRI Research Center will be providing structural brain scans under a second protocol in order to assess changes in the brain associated with both combatives training and concussion.

Organization Name:
Auburn University

Location of Organization: (if foreign location list country)
Partner's contribution to the project (identify one or more)

- ☐ Financial support;
- ☐ In-kind support (e.g., partner makes software, computers, equipment, etc., available to project staff);
- ☐ Facilities (e.g., project staff use the partner's facilities for project activities);
- **X** Collaboration (e.g., partner's staff work with project staff on the project);
- ☐ Personnel exchanges (e.g., project staff and/or partner's staff use each other's facilities, work at each other's site); and
- ☐ Other

Special Reporting Requirements:

None

Collaborative Awards
Nothing to Report

Quad Charts
The Quad Chart (available on https://www.usamraa.army.mil) shall be updated and submitted as an appendix.

Appendices:

Evaluation of the King-Devick Test to Assess Eye Movements and the Performance of Rapid Number Naming in Concussed and Non-Concussed Service Members

Log Number 12089007

W81XWH-14-1-0173

PI: Dr. Michael Dretsch **Org:** The Geneva Foundation **Award Amount:** $403,671

Study/Product Aim(s)

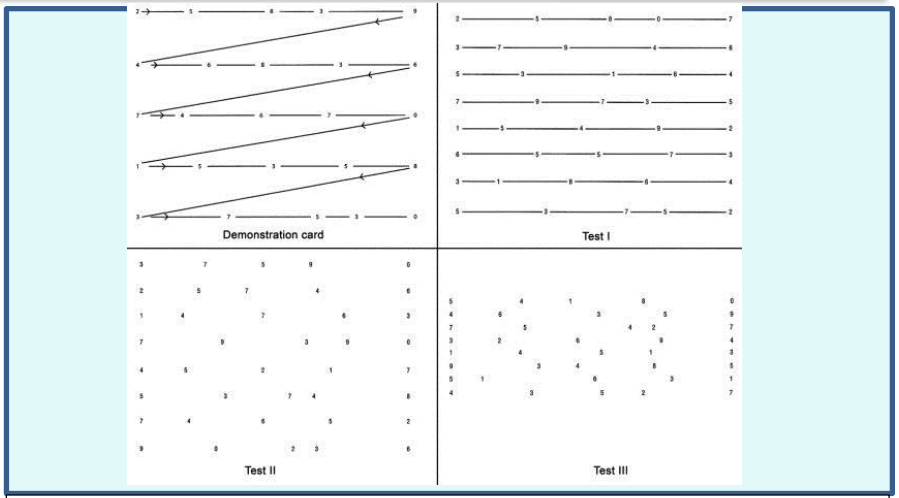
• Main Study Aim is to evaluate the ability of the King-Devick test to accurately detect concussions in Soldiers; Does the Post Incident K-D Test vary from the individual's pre-combatives baseline assessment?

•Additional Aims:

b. Does the pre-combatives baseline K-D Test assessment of individuals who report a history of concussion on their baseline questionnaires vary from the pre-combatives baseline K-D Test assessment of individuals who have not reported a prior concussion event **c. Does the** post-combatives K-D Test assessment vary from the pre-combatives baseline assessment in healthy individuals who do not suffer a concussive event.

Approach

- Subjects will be recruited at the Fort Benning Combatives School, and other Combatives training
- Recruitment will occur on the first day of training during Soldiers' in-processing
- Any Soldier that volunteers to participate will be given the informed consent and HIPAA documents
- Any volunteers that agrees to the consent process will be given a pre-combatives questionnaire and K-D test before training begins
- Volunteers who suffer a concussive event during training will be given a post-incident questionnaire (which includes the MACE and GCS) and K-D test within 24 hours after the event occurs
- Volunteers who do not have a concussive event during training will be given a post-training questionnaire and K-D test on the last day of their training
- Recruitment and testing will be conducted until 100 concussed Soldiers have been tested
- A brain imaging arm of the study will recruit from enrollled subjects, but will occur at Auburn University



Picture above shows the King-Devick test card. Each participant will be start with the demonstration card and continue through each test. Participants are instructed to read the numbers from left to right, and are informed that it is a timed event. Average test time is less than two minutes.

Timeline and Cost

Activities CY	14	15	16	17
Finalizing protocol documents, training employees, meeting with post personnel, and awaiting IRB approval				
Approved protocol. Hire additional study personnel, complete training.				
Data collection; data analysis				
Complete data analysis, and publish findings				
Estimated Budget ($403,671)	**$99,540**	**$201,835**	**$102,295**	

Updated: 19 JULY 2016

Goals/Milestones

CY16 Goals –

- Begin data collection
- Conduct analysis and provide preliminary results

CY17 Goals –

- Finish data collection and analysis by second quarter
- Preparation of reports by third quarter

Comments/Challenges/Issues/Concerns

- Major delays in IRB process.
- Unexpected repairs on RV.

Budget Expenditure as of 6.30.16

Projected Expenditure: $403,671

Actual Expenditure: $181,534